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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,528

12/02/2004

Josef Beden

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JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER

CECIL, TERRY K

ART UNIT

PAPER NUMBER

1723

MAIL DATE

DELIVERY MODE

08/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/516,528	Applicant(s) BEDEN ET AL.	
	Examiner Mr. Terry K. Cecil	Art Unit 1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>one</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following:
 - The abstract of the disclosure is objected to because it contains legal language e.g. “comprising”. See MPEP § 608.01(b).
 - Since claim language is dynamic changing throughout prosecution, references to specific claim numbers in the specification should be removed (e.g. on pages 2-3).

Appropriate correction is required.

Drawings

2. The drawings are objected to because of the following:
 - They fail to comply with 37 CFR 1.84(p)(5) because they do not include the following reference signs mentioned in the description: “62” (page 8, second paragraph).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet”

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pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claims 2 and 20 are objected to because of the following:

- In claim 2, the parenthetical phrase is superfluous and should be removed.
- In claim 20, the phrases “on the one hand” and “on the other hand” are verbose, cloud the understanding of the claim and should be removed.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because of the following reasons:

- In line 3 of claim 1, it is unclear whether “substantially” is meant to describe “insertable” or “consisting” (i.e. the cassette is insertable into the machine *substantially* or the transitional term “substantially consisting of” was intended). It is also unclear what element is “consisting of”, i.e. the apparatus? it (the liquid treatment machine)? or the cassette?

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- Because claim 1 includes three transitional terms (“comprising”, “consisting of”, and “characterized in that”), it is unclear where the preamble ends and the body of the claim begins.
- The following terms lack antecedent basis: “the side” (claim 5); “the frame side” (claim 10); “the machine block” (claims 10, 12, 14 and 16); “the door” (claims 11 and 14); “the frame” (claim 11); “the latched state” (claim 11); “the venting chamber” (claim 20); “the machine side” (claim 20); “the pressing-out phase” (claim 22).
- Regarding claims 10, 13, 16-17 and 25-26, the phrases “optionally” (claims 10, 16 and 25-26); “for example” (claim 13); and “preferably” (claim 17) render the claims indefinite because it is unclear whether the limitations following the phrases are part of the claimed invention. See MPEP § 2173.05(d).
- In claims 8 and 9, the antecedent for “it” is unclear.
- In claim 8, “consisting of” (a closed-ended term) to describe the “pressing actuator system” is unclear and seems to mis-describe the invention since the pressing actuator system necessarily includes more than just an “air cushion”.
- In claim 21, since each pump chamber has only one inlet and one outlet, “inlets” and “outlets” should be singular.
- The balance of the claims are also rejected since they suffer the same defects as the claims from which they depend.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-5, 7 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Pastrone et al. (U.S. 5,431,627), as evidenced by Pastrone U.S. Patent No. 4,927,411, incorporated by reference.

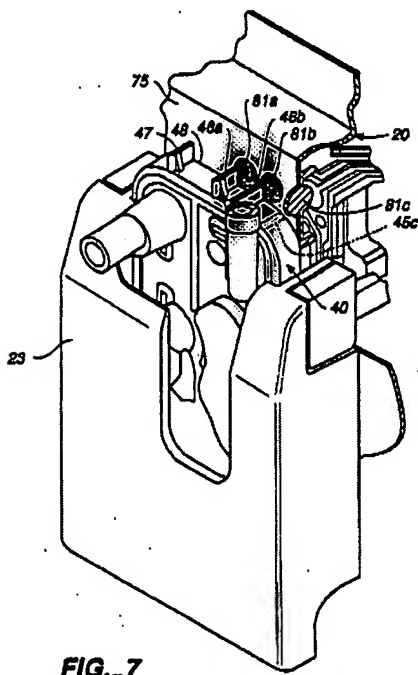


FIG. 7

Regarding claims 1 and 3, Pastrone teaches a liquid treatment machine 20 including cassettes (30, 40, 50, 60) for different applications inserted therein. The cassettes have a rigid body (131, 133) and a foil (elastomeric member 133). The fitted chambers and passages of the cassette are best shown in figures 2-4 of U.S. Patent No. 4,927,411, incorporated by reference into Pastrone (col. 5, line 1-9). It is noted that it is the examiner's interpretation of claim 1 that only 1 cassette is required by the claim language (the recitation of "cassettes" is part of

the intended use). However, figures 2-5 and 2A-5A of Pastrone depict different integration

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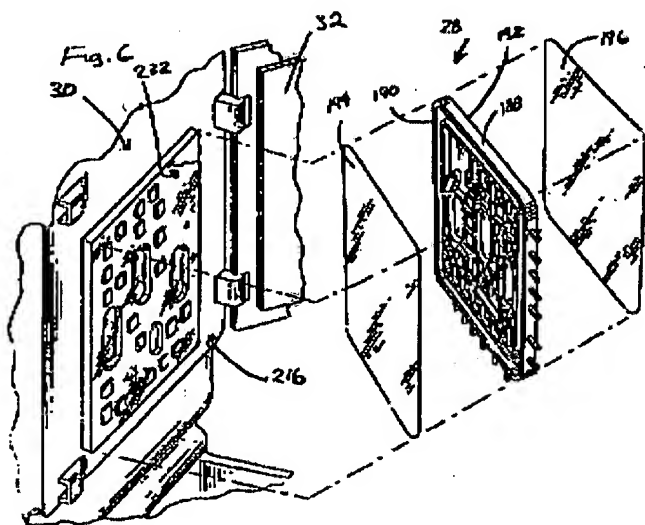
shapes (i.e. different interfacing configurations) resulting from the respective ID flag configurations.

As for claim 2, the cassettes are single use (col. 7, line 4) and are considered to be “disposable”.

As for claim 3, the drug delivery cassettes could be used for acute treatment, e.g. patent controlled delivery of analgesics for acute pain. As for claim 5, the rigid body is molded (see col. 3, line 43 of U.S. 4,927,411 incorporated by reference), wherein a portion thereof e.g. the area of leader of reference no. 34 in figure 2B can be considered a "handle".

As for claim 7, door 23 (figure 1) is fitted to a frame and the cassette is between the door and the “machine block” (e.g. 75). Regarding claim 16, the corresponding surfaces are shown in fig 6.

8. Claims 1-5, 7-9, 12-13, 20 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Westberg et al. (U.S. 7,195,607).



Westburg teaches a blood processing machine including a block 216 receiving a cassette 28 including a “foil” (194). The machine includes actuators (valve actuators PA1-PA4) and sensors (e.g. pressure sensors). It is the Examiner’s position that the phrase “for the operation of the apparatus with the inserted cassette

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such that cassettes can be inserted in different integration shapes” to be an intended use of the apparatus and that claim 1 does not require one than one cassette nor is the cassette required to contact the sensors. As for claim 5, the edge 190 is considered to be a handle. A door 32 includes a latch 218, wherein the block includes a moveable bladder and gasket for pneumatically sealing the cassette between the door and machine block [as in claims 7-9]. The block 216 includes an elastic mat 232 having recesses therein [as in claims 12-13]. A venting chamber 316 is also taught [as in claim 20]. As for claim 27, the single needle is shown in figure 10.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Westberg in view of Burbank et al. (U.S. 7,147,613). Burbank teaches a door sensor 32. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have

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the sensor 32 of Burbank in the invention of Westburg, since such would provide the benefit of confirming the door is secured before enabling circulation.

11. Claims 14, 17 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westburg in view of DE10143137, hereinafter '137. As shown in figure 3, '137 teaches the measuring chamber [as in claim 17] including a nozzle end [as in claim 25]. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the measuring chambers of '137 in the invention of Westburg, since '137 teaches the benefit of measuring parameters of medical fluid in a blood processing machine. As for claim 25, the edge beads for the chambers are shown in figure 35 of Westburg. As shown in 1 and 2, '137 teaches the two part sensor modules.

12. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Westburg in view of '137 as applied to claim 17 above and in further view of Odak et al. (U.S. 6,471,855). Odak teaches a cassette having a rigid base made of polypropylene (col. 9, line 8). It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the base of the cassette of the modified Westburg to be made of polypropylene as in Odak, since Odak teaches the benefit of a material suitable for cassettes.

13. Claims 19 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westburg, as modified above, and in further view of Busby et al. (U.S. 2003/0220607). Busby teaches a cassette rigid base and membrane including polyolefin and polypropylene [0193]

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joined by heat sealing. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the materials of Busby in the invention of the modified Westberg, since Busby teaches the benefit of materials suitable for the construction of a medical cassette. Welding is a well-known heat sealing technique.

14. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Westberg, in view of Bryant et al. (U.S. 5,474,683). As shown in figure 7, Bryant teaches a frame having projections received within the "cutout" (the area between the flanges around the periphery of the cassette (see figure 3, adjacent the leader of 24) of the cassette. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the projections/cutout configuration of Bryant in the invention of Westberg, since Bryant teaches the benefit of retaining a cassette in a medical fluid apparatus in the desired positioned.

15. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Westberg. Westberg teaches cassette in various configurations, e.g. 28 and 28'. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have a set of cassettes in order to have the benefit of performing a variety of different blood processing procedure in association with the device shown in figure 1 (col. 4, lines 41-44).

16. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Westberg in view of Kamen et al. (U.S. 5,628,908). Westberg teaches a venting unit of the treatment machine but

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doesn't teach such coupled to a gas-permeable membrane integrated into the cassette. However, such is taught by Kamen.

The pump inlet 154 and the pump outlet 156 communicate with ambient air via a common vent 158 (shown schematically in FIG. 23). The vent 158 includes a filter (membrane) 160 that removes particulates from the air drawn into the pump 84.

As described, the filter of Kamen is permeable to gas. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the vent/filter of Kamen as part of the venting unit of Westberg, since Kamen teaches the benefit of venting the pumps (chambers).

17. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Westberg in view of Bellotti et al. (U.S. 4,436,620). Bellotti teaches a dialyzer 38 that is integrated (forming a unit with) a cassette. The dialyzer can be grasped and could therefor be used as a handle. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have the dialyzer as part of the cassette of Westberg since such would provide the benefit of a unit for ease/efficiency when installing or replacing the parts.

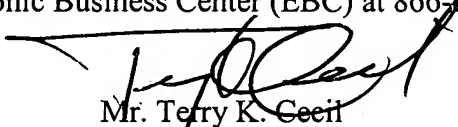
18. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westberg, as modified above, and in further view of Bilstad (U.S. 4,479,762)). As in figures 19A-19C, Bilstad teaches a substantially spherical pump chamber 134 having the modified radius to allow for a passage (it is the Examiner's position that merely naming the passage a "flush" passage fails to further limit the apparatus beyond the elements cited. It is considered that it would have been obvious to one ordinarily skilled in the art at the time of the invention to have

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the pump chamber of Bilstad in the invention of the modified Westberg, since Bilstad teaches the benefit of a self-contained prepackaged fluid processing module which can be conveniently stored, set-up and operated (col. 1). Also, it is contended that the line of the inlet/outlet is tangent to the curve of the pump chamber.

19. Contact Information:

- Examiner Mr. Terry K. Cecil can be reached at (571) 272-1138 at the Carlisle campus in Alexandria, Virginia for any inquiries concerning this communication or earlier communications from the examiner. Note that the examiner is on the increased flextime schedule but can normally be found in the office during the hours of 8:30a to 4:30p, on at least four days during the week M-F.
- David R. Sample, the examiner's supervisor can be reached on 571-272-1376, if attempts to reach the examiner are unsuccessful.
- The Fax number for this art unit for official faxes is (571) 273-8300.
- Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mr. Terry K. Cecil
Primary Examiner
Art Unit 1723

TKC
August 7, 2007